K004044

MAR - 2 2001

## 510(k) Summary

# HomMed Sentry III Patient Monitor System

Contact: Herschel Peddicord, President
HomMed, LLC
19275 West Capitol Dr., Suite 200
Brookfield , WI 53045
414 783-5440 Voice
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Trade Name: HomMed Sentry III Patient Monitor System

Common Name: Patient Vital Signs Monitor

Classification Name: Patient Monitor

Substantial Equivalence is Claimed to:
HomMed Sentry I Patient Monitor System and the HomMed Ultegra™ Patient Scale and Communication System

Device Description: The HomMed Sentry III Patient Monitor System is a portable patient vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. In addition, the system has optional glucometry and spirometer measuring capabilities. The Sentry III Patient Monitor acquires the patient vital signs data and displays it. The data can also be transmitted via the communication system through the Skytel Pager Network to a central station for storage with retrospective display and analysis.

Indications for Use: The HomMed Sentry III Patient Monitor System is intended for in home and/or healthcare facility applications under physician orders. The use of the system is to allow retrospective review of certain patient physiological functions. The HomMed Sentry III Patient Monitor System can measure and display patient data including noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. Additionally, the patient vital signs data can be communicated to a central review station via a pager network with a backup landline telephone modem for telephone communication with the central pager network if necessary.

The HomMed Sentry III Patient Monitor System provides a noninvasive blood pressure (NIBP) monitor for measurements of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures; pulse oximeter, acquires a pulse rate using an oximeter: oral temperature via an electronic thermometer; weight from an electronic scale. All data collected from these functions as well as optional glucometry and spirometry is sent through an internal communication module. The device will provide fast, reliable measurements on patients ranging from children (pediatrics) to adults when using the appropriate blood pressure cuff. The pulse oximetry works with Sentry III Patient

Monitor System pulse oximetry probes provided by HomMed, providing Sp02 and pulse rate on all patients from pediatric to adult. The electronic thermometry requires use of the Welch Allyn oral thermometry probe and probe covers. It provides only oral temperature information. The device is intended for use in the patient home and/or clinical environments by the patient as prescribed by or on orders by a physician with the information transmitted to a central viewing station where healthcare professionals can review the data.

Comparison with Predicate Devices:

This HomMed Sentry III Patient Monitor System allows uncomplicated measurement and remote monitoring of patient vital signs including weight utilizing the existing technologies of the predicate devices: HomMed Sentry I Patient Monitor System and Ultegra Scale and Communication Systems

Determination of Substantial Equivalence:

The performance of each component of the HomMed Sentry III Patient Monitor System has been confirmed to be equivalent to the predicate devices HomMed Sentry I Patient Monitor System and HomMed Ultegra Scale and Communication Systems. In addition, the HomMed device continues to utilize an external medical grade power supply ensuring the continued protection and safety for the patient vital signs monitor, scale and communication module.

Compliance to Standards and Regulations:

The HomMed Model Sentry III Patient Monitor System complies with the following national and international standards:

| | | |
|---|---|---|
| Safety | EN 60601-1 | Medical Electrical Safety |
| | IEC 601-1-2 | EMC Compliance |
| | ISO 10993-5,10-11 | Biocompatibility |

Performance Data:

The HomMed Sentry III Patient Monitor System utilizes the HomMed Sentry I and the HomMed Ultegra Scale and Communication System within the environments for which Sentry I are marketed. The Sentry III Patient Monitor System performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed demonstrating compliance with applicable standards. The test results demonstrated that the System is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

The HomMed Sentry III Patient Monitor System performance is consistent with the HomMed Sentry I System performance and the HomMed Ultegra Scale and Communication System and additional testing has been done on the HomMed Sentry III Patient Monitor System patient monitor assuring compliance with applicable electrical, safety and healthcare standards. Thus it is the HomMed position that the HomMed Sentry III Patient Monitor System performs as well as the legally marketed predicate devices.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2001

Mr. Herschel Peddicord, President
HomMed, LLC
19275 West Capitol Dr., Suite 200
Brookfield, WI 53045

Re: K004044
Trade Name: HomMed Sentry III Patient Monitor System
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: December 27, 2000
Received: December 29, 2000

Dear Mr. Peddicord:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

**510(k) Number (if known):** K004044

***Device Name: HomMed Sentry III Patient Monitor System***

## Indications for Use

The HomMed Sentry III Patient Monitor System is intended to be only under or with physicians orders to measure Patient Vital Signs in home environments by patients as well as in clinical environments by health care providers to measure patient vital signs. The HomMed Sentry III Patient Monitor System is available for home uses with doctors' orders only. The patient vital signs data is collected and displayed by the HomMed Sentry III Patient Monitor System. In addition, the data can be transmitted via the communication module to a central station where the patient vital signs data can be viewed and analyzed.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004044